Jan 09, 2026

Traditional Chinese Medicine as add-on treatment of triple/quadruple therapy for Helicobacter pylori infection: an overview of systematic reviews and meta-analyses (Protocol)

DOI
https://dx.doi.org/10.17504/protocols.io.6qpvry42pgmk/v1

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Protocol Citation: Xiao-Bei Si, Lei Qiao, Xiao-Lu Chen, Xu-Min Zhang, Yu Lan 2026. Traditional Chinese Medicine as add-on treatment of triple/quadruple therapy for Helicobacter pylori infection: an overview of systematic reviews and meta-analyses (Protocol). **protocols.io** https://dx.doi.org/10.17504/protocols.io.6qpvry42pgmk/v1

Protocol status: Working
We use this protocol and it's working

Created: January 08, 2026

Last Modified: January 09, 2026

Protocol Integer ID: 238234

Keywords: traditional Chinese medicine, Helicobacter pylori, systemic review, western medicine on helicobacter pylori infection, helicobacter pylori infection, quadruple therapy for helicobacter pylori infection, chinese medicine, traditional chinese medicine, chinese medical database, overview of systematic review, methodological quality of these systemic review, meta analyses with comparison, meta analysis, systematic review, meta analyses with variable result, been many relevant systemic review, methodological quality of these sr, systemic review, many relevant systemic review, western medicine, databases of medline, evidence quality characteristic, clinical evidence

Funders Acknowledgements:
Beijing Jishuitan Hospital Nova Program
Grant ID: XKXX202205

Abstract

Background: In recent years, many studies reported the anti-Hp effects of Traditional Chinese Medicine. Based on these studies, there had been many relevant systemic reviews and meta analyses with variable results **Aim: This overview aims to investigate the general characteristics and assess the methodological quality of these systemic reviews/meta ana lyses (SR/MAs). **Method:** In this overview, we intend to includ systemic reviews/meta analyses with comparison of Chinese medicine and western medicine on helicobacter pylori infection by searching databases of Medline, Embase, Web of Science, China National Knowledge Infrastructure Database (CNKI), Chinese VIP Information (VIP), Chinese Medical Databases (CMB) and Wan-Fang Database until January 6st, 2026. AMSTAR 2 and GRADE system tools will be adopted to assess the methodological quality and evidence quality characteristics. **Conclusion:** The methodological quality of these SR/MAs will be assessed as clinical evidence and our result may help further use of them.

Attachments

PDF

protocol (1).pdf

253KB

Guidelines

Source of literature and search strategy

We intend to perform a systemic literature search in the databases of MEDLINE, EMBASE, Web of Science, China National Knowledge Infrastructure Database (CNKI), Chinese VIP Information (VIP), Chinese Medical Databases (CMB) and Wan-Fang Database until January 6th, 2026. The articles of academic journals, dissertation and conference proceedings will also be included as well irrespective of gray literature status. The search strategies for electronic databases are listed in Appendix 1 (taking PubMed as an example). What's more, the reference lists of studies will also be searched for potentially relevant titles.

Inclusion and Exclusion criteria

The following criteria will used for literature selection, and the studies that meet the criteria are eligible for further overview. (1) Patients: The subjects enrolled were Hp infectors with/without Hp related diseases such as gastritis, ulcer, etc. The diagnosis of Hp infection accord with guidelines of "Fifth Chinese National Consensus Report on the management of Helicobacter pylori infection". (2) Interventions: The subjects in Treatment group underwent interventions of Traditional Chinese Medicine combined with PTT or BCQT. The Chinese medicine included Chinese herb medicine, Chinese proprietary medicine but not Chinese herbal medicine extractives. (3) Control: The subjects in control group underwent therapies of PTT or BCQT only. (4) Outcomes: The main outcome was eradication rate. The secondary outcome could be side effect rate, relief of digestive symptoms (remission rate), and healing of ulcer (healing rate and total effectiveness rate). (5) Study type: The study design consisted of a systemic review and/or meta analyses (SR/MA).

The studies that meet these criteria will be excluded: (1) The articles of redundant publications; (2) The studies that did not complement calculation of meta-synthesis although titled "meta-analysis" or "systemic review". (3) Systemic reviews of studies in vitro; (4) Articles published as abstracts or protocols no matter their publication types.

Methods

1 Perform a systemic literature search in the databases of MEDLINE, EMBASE, Web of Science, China National Knowledge Infrastructure Database (CNKI), Chinese VIP Information (VIP), Chinese Medical Databases (CMB), and Wan-Fang Database until January 6st, 2026. Include articles from academic journals, dissertations, and conference proceedings irrespective of gray literature status.

2 Search strategies for electronic databases are listed in Appendix 1 (taking PubMed as an example). Additionally, search the reference lists of studies for potentially relevant titles.

3 Use the following criteria for literature selection:

3.1 Patients: Subjects enrolled were Hp infectors with/without Hp related diseases such as gastritis, ulcer, etc. Diagnosis of Hp infection must accord with guidelines of the “Fifth Chinese National Consensus Report on the management of Helicobacter pylori infection”.

3.2 Interventions: Subjects in the Treatment group underwent interventions of Traditional Chinese Medicine combined with PTT or BCQT. The Chinese medicine included Chinese herb medicine, Chinese proprietary medicine but not Chinese herbal medicine extractives.

3.3 Control: Subjects in the control group underwent therapies of PTT or BCQT only.

3.4 Outcomes: The main outcome was eradication rate. Secondary outcomes could be side effect rate, relief of digestive symptoms (remission rate), and healing of ulcer (healing rate and total effectiveness rate).

3.5 Study type: The study design consisted of a systemic review and/or meta analyses (SR/MA).

4 Exclude studies that meet the following criteria:

4.1 Articles of redundant publications.

4.2 Studies that did not complement calculation of meta-synthesis although titled “meta-analysis” or “systemic review”.

4.3 Systemic reviews of studies in vitro.

4.4 Articles published as abstracts or protocols no matter their publication types.

5 All retrieved trials will be screened by 2 reviewers independently in steps. Step 1, a potential screening of titles and abstracts will be implemented for relevant articles. Step 2, full text screening will be retrieved for further assessment according to the inclusion and exclusion criteria. The plan for solving disagreement is discussing or consulting of another specialist.

6 Two reviewers independently extract the data from including SR/MAs with the items of authors, publication year, sample size, intervention in groups, main outcome of eradication rate and secondary outcomes (remission of digestive symptoms, healing of digestive ulcers and side effects). Piloted forms will be built for data extraction.

7 Two reviewers assess the quality of each included review independently. Assessment of Multiple Systematic Review 2 (AMSTAR 2) scale will be adopted for assessment of methodological quality. A piloted form will also be built for data extraction and further assessment.

8 The Grades of Recommendations, Assessment, Development and Evaluation (GRADE) approach was used to assess the level of evidence and summarize each outcome by two reviewers independently.

9 Eradication rate was defined as negative rate after eradication therapy. Healing of ulcers was divided into 3 grades, i.e. curing, effectiveness and non-effectiveness, according to endoscopy examinations before and after eradication therapy. Curing was defined as disappear of ulcer lesion and inflammatory manifestation around. Effectiveness meant ulcer lesion narrowed to be less than 50%. Non-effectiveness meant ulcer narrowed but still more than 50%. Healing rate was defined to be ratio of curing numbers and total numbers (Healing rate=curing number/total number × 100%). Total effectiveness rate of ulcer was defined as percentage of patients with curing, effectiveness (Total effectiveness rate=[(total number – non-effectiveness number)/total number × 100%]). Total remission rate of digestive symptoms was defined as the percentage of patients with relief of any digestive symptoms. Side effect rate was defined to be the percentage of patients with at least one side effect.

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